consumers will accept a useful product that poses no unreasonable risk.¹⁷ Thus, under any of the three tests, ZAI would not be a defective product if it poses no unreasonable risk.

b. Causation

If there is no reliable scientific evidence establishing any unreasonable health risk from ZAI, claimants cannot demonstrate that any defect in ZAI has caused actionable injury. See. e.g., Gaulding v. Celotex Corp., 772 S.W.2d 66, 69-70 (Tex. 1989) (plaintiffs bear the burden of proving causation); Magistrini v. One Hour Martinizing Dry Cleaning, 109 F. Supp. 2d 306, 311 (D. N.J. 2000) ("Plaintiff must demonstrate that the defect in the product was a proximate cause of the injury.").

c. Economic Loss

Another issue common to ZAI claims is whether claimants can recover economic losses in the absence of tort damages. The "economic loss doctrine," which arises from the Uniform Commercial Code and is accepted across all jurisdictions, bars recovery in tort of purely economic losses — *i.e.*, those arising from repair or replacement of commercial goods or from consequential damages. Even if a product fails to perform adequately, the economic loss doctrine precludes claims in tort where the only losses are product failure and the consequential damages of product

Among other things, products whose asbestos emissions fall within applicable regulatory guidelines are not defective. See, e.g., Dartez v. Fibrehoard Corp., 765 F.2d 456, 470 (5th Cir. 1985) ("Compliance with ... government safety standards constitutes strong evidence that a product is not defective."); Gideon v. Johns-Manville Sales Corp., 761 F.2d 1129, 1144 (5th Cir. 1985) (same). Similarly, such exposures do not meet the tort-law threshold of causation. See, e.g., Dartez, 765 F.2d at 470-71 (evidence of causation insufficient where product's asbestos emissions below OSHA permissible exposure levels); Gideon, 761 F.2d at 1145 (citing OSHA standards and concluding that defendant's asbestos gaskets, textile products and packing materials were not a substantial factor in causing disease: "there was no evidence that the inhalation of the relatively small amounts of asbestos fibers possibly released during the handling of Raymark products was a substantial factor in causing [the plaintiff's] present condition"); Quick v. Murphy Oil Co., 643 So.2d 1291, 1296-97 (La. App. Ct. 1994) (defendant's asbestos-containing products were not "a substantial cause" of plaintiff's disease where "asbestos emissions were below the threshold values established by OSHA").

failure. See, e.g., Adams-Arapahoe Sch. Dist. v. GAF Corp., 959 F.2d 868, 872 (10th Cir. 1992). Here, ZAI has functioned adequately as insulation for decades. If, as Grace contends, there is no reliable scientific evidence of unreasonable product risk, then no claimant can establish separate tort damages from the product. Claims for repair and replacement of the product would be barred as a matter of law.

3. Grace Has Proposed A Straightforward Litigation Protocol For ZAI Claims.

Grace has proposed a fair and expeditious procedure for resolution of ZAI claims.

The protocol is as follows:

- Once the bar date has passed, the Court would appoint a ZAI litigation committee.
- The parties will then litigate the issue of whether reliable scientific evidence demonstrates that ZAI poses an unreasonable a risk. The Court can determine whether to appoint an expert panel.
- At the conclusion of discovery, Grace will file an omnibus objection and *Daubert* summary judgment motions. 18

Courts have routinely granted summary judgment to toxic tort defendants after excluding expert causation evidence under *Daubert. See. e.g., Allison v. McGhan Medical Corp.*, 184 F.3d 1300, 1304 (11th Cir. 1999) (upholding grant of summary judgment in breast implant case given "inability to establish liability without the experts" after testimony excluded under *Daubert*); *Cabrera v. Cordis Corp.*, 134 F.3d 1418. 1419 (9th Cir. 1998) (upholding grant of summary judgment after expert testimony that brain shunt manufactured by defendant was defective and that silicone

Once an objection is lodged, the underlying burden is on the claimant to show, by a preponderance of the evidence, that the claim is valid. "[T]he claimant in any objection hearing retains the burden of persuasion. . . [Once a sufficient objection to a claim is made] the burden of proof must then be met by the claimant by a preponderance of the evidence." 9 Collier on Bankruptcy ¶ 3001.09[2] at 3001–26 (15th ed. revised): accord In re Harrison, 987 F.2d 677, 680 (10th Cir. 1993); In re Allegheny Int 'I, Inc., 954 F.2d 167, 173–74 (3d Cir. 1992); In re Consumers Realty & Dev. Co., 238 B.R. 418, 423 (8th Cir. B.A.P. 1999).

components in the shunt made plaintiff ill); Allen v. Pennsylvania Eng 'g Corp., 102 F.3d 194, 195-96 (5th Cir. 1996) (trial court properly excluded scientifically invalid expert testimony asserting that exposure to ethylene oxide caused cancer); Barrett v. Atlantic Richfield Co., 95 F.3d 375, 382 (5th Cir. 1996) (plaintiff expert's "proposed testimony concerning cotton rat study does not satisfy Rule 702's 'standard of evidentiary reliability,' as interpreted by Daubert, because [expert's] testimony would consist of 'unsupported speculation'"); Siharath v. Sandoz Pharms. Corp., 131 F. Supp.2d 1347, 1371 (N.D. Ga. 2001) ("exclud[ing] the expert's testimony and grant[ing] summary judgment"); Glastetter v. Novartis Pharms. Corp., 107 F. Supp.2d 1015 (E.D. Mo. 2000)(granting summary judgment where testimony of plaintiff's experts that plaintiff's post-partum ingestion of the drug Parlodel caused her injury was not sufficiently reliable to be admissible under Daubert), aff'd, 252 F.3d 986 (8th Cir. 2001); Hollander v. Sandoz Pharms. Corp., 95 F. Supp.2d 1230, 1232 (W.D. Okla. 2000) (granting summary judgment where "plaintiffs evidence of causation fails the test for scientific reliability set forth in Daubert); Cuevas v. E.I. DuPont de Nemours & Co., 956 F. Supp. 1306, 1312-13 (S.D. Miss. 1997) (testimony of treating physicians and toxicologist regarding temporal relationship between alleged exposure to spray and plaintiff's medical condition inadmissible under Daubert or Rule 702). 19

Although Grace maintains that ZAI property damage claims are invalid and should be disallowed on summary judgment, if the Court denies any motions for summary judgment, the

Bankruptcy courts have likewise excluded expert testimony under *Daubert* before ruling on the merits of the parties' claims and defenses. *See. e.g.. In re Canvas Specialty, Inc.*, No. LA 00-33180, 2001 WL 336463, at *3-*4 (Bankr. C.D. Cal. Mar. 28, 2001): *In re Husting Land & Dev., Inc.*, 255 B.R. 772, 780-81 (Bankr. D. Utah 2000): *In re Dow Corning Corp.*, 237 B.R. 364 (Bankr. E.D. Mich. 1999). As a bankruptcy court recently explained in excluding one party's expert and granting summary judgment for the other party, "when dealing with expert testimony in a summary judgment motion (as well as at trial), the trial court does have the ability – indeed, the duty – to determine if expert testimony should be admitted in the first instance." *In re Bonham.* 251 B.R. 113, 133 (Bankr. D. Alaska 2000) (emphasis omitted).

Procedure 42(a) allows for just such a procedure, giving the Court a "broad grant of authority" and power "to expedite the trial and eliminate unnecessary repetition and confusion." *In re Air Crash Disaster at Florida Everglades on December 29, 1972*, 549 F.2d 1006, 1013 (5th Cir. 1977); see also In re Fibreboard Corp., 893 F.2d 706, 708 (5th Cir. 1990).

Courts in a variety of circumstances have consolidated claims under Rule 42 to resolve common, threshold issues. See, e.g., In re Paoli R.R. Yard PCB Litig., 113 F.3d 444, 452 & n.5 (3d Cir. 1997) (observing that "exercising its discretion under Federal Rule of Civil Procedure 42(b)," district court ordered consolidated trial on "issues of exposure, causation, medical monitoring, and property damages" which served "the interests of judicial economy"); In re Dow Corning, 211 B.R. 545, 583 (Bankr. E.D. Mich. 1997) (consolidation of breast implant tort claims for generic causation trial appropriate to resolve "a threshold issue which, depending on its resolution, could obviate the need for further proceedings"); In re Bendectin Litig., 857 F.2d 290, 317 (6th Cir.1988) (affirming consolidated trial on causation and observing: "Many courts have ... permitted separate issue trials when the issue first tried would be dispositive of the litigation. . . . [T]he plaintiffs can never win a case if they can't prove the [defendant's] drug caused the problem. That is a central issue in this case.... [A]ll claims depended upon the answer to a single question: Does Bendectin, taken in therapeutic doses cause birth defects?"), cert. denied, 488 U.S. 1006 (1989); In re Beverly Hills Supper Club Fire Litig., 695 F.2d 207, 217 (6th Cir. 1982) (affirming consolidation under Rule 42 for trial on causation), cert. denied, 461 U.S. 929 (1983).

B. MK-3 Property Damage Claims: Again There Are Threshold Liability Issues.

The second claim category, MK-3 property damage claims, likewise can be adjudicated efficiently by focusing on common issues. As noted in Grace's opening brief, there has been extensive litigation regarding MK-3. Few claims remain, and if and to the extent that a significant number of new claims are made in the bankruptcy proceedings, it is now possible to address such claims initially on an aggregated basis.

Specifically, common issue litigation is called for in two areas. *First*, the statute of limitations defense — based on the doctrine of constructive notice — could dispose of all or most MK-3 claims. Past litigation and regulatory history show that building owners and others have known for years about the characteristics of MK-3. In such circumstances, courts have found that constructive (and sometimes actual) knowledge triggers the statute of limitations and precludes claims. *Second*. MK-3 claims, like those involving ZAI, turn on the issue of risk. Although MK-3 has been the subject of significant litigation in the past, none of those claims was tested under *Daubert*. Now, however, the parties have both substantial data and a developed *Daubert* doctrine and can address the issue of whether reliable scientific evidence shows that MK-3 poses a demonstrably unreasonable risk to building occupants. As with ZAI, if there is no reliable scientific evidence of unreasonable risk, Grace is entitled to summary judgment on the common issues of product defect, causation, and economic loss.

1. The Statute Of Limitations

The first issue appropriate for resolution at the summary judgment stage is whether MK-3 claims are barred by the statute of limitations. The PD Committee does not quarrel with Grace's description of the history of MK-3 regulation and litigation. MK-3 was a spray-applied,

cementitious fireproofing product marketed primarily for application to the skeletal steel-beam structure of commercial buildings during construction. MK-3 contained more than 1% asbestos, and as of July 4, 1973, the EPA banned the spraying of such products. By that date, however, Grace already had made a transition to substitute products MK-4 and MK-5, which had no commercially added asbestos. Also in 1973, the EPA issued the National Emission Standard for Hazardous Air Pollutants (Asbestos, Beryllium, and Mercury). Although that standard originally applied only to demolition of commercial buildings, it was amended two years later to include renovation as well. See Prudential Ins. Co. of America v. United States Gypsum Co., 146 F. Supp. 2d 643, 667 (D.N.J. 2001). Such EPA decisions and standards made public and commercial building owners aware of MK-3, its characteristics, and the EPA's position.

The crucial question for common resolution is whether building owners can be charged with constructive knowledge of their claims, thereby triggering the statute of limitations. This very topic — the legal impact of the long-pervasive knowledge concerning potential hazards of asbestos use in commercial buildings — recently was analyzed in detail in the *Prudential Insurance Co.* case, 146 F. Supp. 2d 643 (D.N.J. 2001). There, building owners brought claims against manufacturers of asbestos-containing products seeking to recover costs of monitoring and/or removing the products from the buildings. The court found that the statute of limitations had run on the building owners' claims because they had constructive notice and should have known of the products' asbestos properties when the EPA issued numerous advisories about them years earlier.

See id. at 666 (given "the EPA's repeated warnings about the potential hazards of in-place asbestos, the court concludes that such events should have triggered Prudential's inquiry into the hazards

²⁰ The limitations period for asbestos property damage claims is typically three years. *See, e.g.*, Cal. Code Civ. Pro. § 338; D.C. Code Ann. § 12-301; N.Y. C.P.L.R. § 214-c.

posed by asbestos"). Notably, the court determined that such inquiry notice trumped the building owners' claim that they had no actual notice of asbestos hazards: "While Prudential demonstrates that a dispute exists as to whether it actually knew of its injuries, it does not demonstrate that such a dispute exists as to whether it *should have* known of its injuries prior to October 11, 1983." *Id.* at 669. (emph. added)

The conclusions reached in *Prudential* should be fully applicable here. Asbestos-related litigation and environmental advisories have been reported nationally for years. *See Prudential*. 146 F. Supp. 2d at 671 ("With the rising public awareness of asbestos hazards, most any building owner would be hard pressed to justify no reasonable knowledge of the hazard [by 1983]."). Moreover, the doctrine of constructive notice that was applied in *Prudential* is recognized broadly across jurisdictions. Thus, it is within this Court's power to determine the date by which a reasonable claimant knew or should have known of potential claims. Such a finding properly can eliminate entire classes of MK-3 claims—even if the statutes of limitation vary among jurisdictions.

2. Product Defect, Causation And Economic Loss

The issues of product defect, causation and economic loss apply as readily to MK-3 claims as they do to ZAI claims. Extensive analysis and extensive litigation have revealed no reliable scientific evidence demonstrating that MK-3 in commercial settings poses any unreasonable risk of harm to building occupants or maintenance workers. Notably, a comprehensive 1992 study published by a Grace expert in a peer reviewed journal summarized the analysis of 2892 air samples from 315 public, commercial, residential, school and university buildings. Exposure to asbestos was found to be virtually nonexistent and far below federal standards.

The data reported herein indicate that average ambient levels in buildings containing [asbestos-containing materials] are far below (typically on the order of 1000-fold less) federal action levels. It should also be kept in mind

that the action levels themselves are considerably below any levels that have been shown to cause disease in humans. Further the data presented herein indicate that many of the indoor locations sampled have airborne fiber levels that are below the 0.01 USEPA clearance level.

R.J. Lee et al., Exposure to Airborne Asbestos in Buildings, 16 Regulatory Toxicology and Pharmacology 93, 106 (1992). The authors noted that their findings confirmed those of several earlier studies, including the EPA's own public buildings study. See id.

Under *Daubert*, claimants must come forward with reliable scientific evidence demonstrating an unreasonable risk from MK-3. Grace submits that claimants will not be able to make this threshold showing, and therefore will not be able to establish existence of a product defect or causation. By the same token, claimants will be unable to establish non-economic (*i.e.* tort) damages, thereby precluding recovery pursuant to the economic loss doctrine.

3. Grace Has Proposed A Straightforward Litigation Protocol For MK-3 Property Damage Claims.

As with ZAI claims, Grace has proposed a legally sound and efficient protocol for the resolution of MK-3 claims:

- After the bar date passes, Grace will move for summary judgment on (a) the issue of statute of limitations based upon constructive notice, and (b) res judicata;
- The statute of limitations motion can be decided as a matter of law and can eliminate those claims not filed within three years (or the appropriate statutory period) from the date of constructive notice. The *res judicata* motion can be decided as a matter of law based upon prior settlements.
- If any claims survive the statute of limitations and *res judicata* motions, proceedings under *Daubert*. Rule 56 and Rule 42 would be held to determine whether reliable scientific evidence demonstrates that MK-3 poses an unreasonable risk to occupants of commercial buildings; and
- If claims survive the foregoing process, and are not otherwise resolved, case-specific adjudication can commence.

C. Personal Injury Claims: Many Claims Fail To Meet Basic Legal Requirements.

The third and final category of claims to be resolved — personal injury claims — also lends itself to common issue adjudication. The task of any personal injury litigation protocol must be to separate valid claims from those brought by the uninjured or those whose injuries were not caused by Grace's products. Based upon Grace's litigation history and sample claims it already has analyzed, many claimants will be unable to meet the basic requirements of a cause of action for personal injury.

1. Certain Legal Requirements Are Suitable For Adjudication On A Common Basis.

Claimants bear the burden of proving injury and causation by a preponderance of the evidence. See. e.g., Vigiolto v. Johns-Manville Corp., 643 F. Supp. 1454 (W.D. Penn. 1986), aff'd, 826 F.2d 1058 (3d Cir. 1987); See also Thompson v. Johns-Manville Sales Corp., 714 F.2d 581 (5th Cir. 1983); Marshall v. Celotex Corp., 651 F. Supp. 389, 394-95 (E.D. Mich. 1987); Gaulding v. Celotex Corp., 772 S.W.2d 66 (Tex. 1989). Grace submits that summary judgment proceedings on the common issues of (a) product identification and exposure, (b) dose sufficient to cause disease, (c) compensable injury and (d) lack of reliable diagnostic evidence will demonstrate that many claimants are unable to establish these basic elements of a personal injury claim.

a. Product Identification And Product Exposure

As set forth in Part I of this brief, product identification is a massive problem with regard to the personal injury claims against Grace. The recent sampling of 1997 and 2000 claims shows that few claimants worked in industries and occupations in which they could even have been exposed to Grace asbestos products. Under the law, the inability to demonstrate actionable exposure to Grace product dooms any such claim.

There can be no personal injury claim unless the plaintiff establishes exposure to defendant's product or material. See generally PROSSER & KEETON ON TORTS § 103, at 713 (5th ed. 1984) (an essential element of a plaintiff's case is "the identification of the named defendant as the manufacturer or supplier of the defective product"). In asbestos cases, the claimant must establish first that he or she worked at a job site where the defendant's asbestos was present. "It is axiomatic that, if the defendant never sold asbestos to any of the locations where [the claimant] was allegedly employed, no cause of action lies against defendant." Outlaw v. Keene Corp., No. 88-9490 1990, U.S. Dist. LEXIS 1245, at *3-4 (E.D. Pa. Feb. 5, 1990).

Product identification has been highly controversial in asbestos cases in the tort system, as reflected by widely reported incidents of witness coaching²¹ and of testimony "abruptly shift[ing]" in response to bankruptcy filings.²² Grace intends to move for summary judgment against any claimant who cannot produce any identification of a Grace product as his or her work site.

²¹ See, e.g., L. Brickman & R. Rotunda, When Witnesses Are Told What to Say, WASH.POST, Jan. 13, 1998, at A15: Rogers, Witness Preparation Memos Raise Questions About Ethical Limits, 14 ABA/BNALAWYERS MANUAL ON PROF. CONDUCT 48, 48-50 (1998) (20-page document from one plaintiffs' asbestos law firm "provides detailed information about asbestos products and packaging; instructs witnesses how to deal with questions and issues at the deposition: gives a list of health symptoms that could enhance damages; and provides general information and advice about being deposed. The document does not mention a witness's obligation to tell the truth."); Accidental Exposure, HARPER'S, 296 (1772) (1/1/98) (containing text of the memo): 30 TEX. TECH. L. REV. 1471, 1476 (1999) (former Texas Supreme Court justice terming the memorandum a "cancer on the legal system").

Notably, when major asbestos producers such as Johns-Manville sought Chapter 11 protection years ago, claims — and testimony — shifted away from the primary manufacturers to more peripheral defendants who remained outside Chapter 11. Whereas "prebankruptcy testimony in Philadelphia Naval Yard Cases put Manville's share of product use as high as 80 percent, postbankruptcy testimony had Manville exposure accounting for a quarter or less of the volume of asbestos-containing materials encountered by plaintiffs." L. Brickman. The Asbestos Claim Management Act of 1991, 13 CARDOZOL, REV. 1891, 1917 n.13 (1992); see also id. at 1894 n.13 (noting that after the Johns-Manville filing, "plaintiffs' testimony (and that of their witnesses) abruptly shifted from a predominantly Manville exposure frame to a predominantly 'other defendants' exposure").

b. Exposure Sufficient To Cause Disease

A second significant problem, arising both in prior litigation and in the sample claims noted above, is the lack of evidence of dose and exposure sufficient to cause harm. In toxic tort cases, merely working at a site where an asbestos product was present does not give rise to a cause that is sustainable under the Federal Rules of Evidence. The plaintiff must show that he or she was exposed to defendant's allegedly hazardous product or material and that such exposure proximately caused injury.

It is a fundamental tenet of science that "the dose makes the poison." Any substance can be harmful in a large enough dose. Conversely, many substances that are known to be harmful at high doses – such as aspirin – are harmless at lower doses. This is true with asbestos as with all other chemicals. Virtually every person in North America has been exposed to asbestos. Indeed, pathology data show that individuals in the general population have thousands, even millions, of asbestos fibers in their lungs with no adverse effect. According to Dr. Andrew Churg, a leading pathologist of asbestos diseases. "one may find as many as 40 million fibers of chrysotile, 40 million fibers of tremolite, and 400,000 fibers of amosite or crocidolite in the lungs of the general population of Vancouver, along with 40,000 asbestos bodies." Even so, "there is no evidence that this fiber burden produces asbestos-related disease in the general population."

This principle, first articulated by Paracelsus in the sixteenth century, is one of the foundations of modern toxicology. In the words of Paracelsus: "What is there that is not poison? All things are poison and nothing [is] without poison. Solely the dose determines that a thing is not a poison." See Casarett and Doull's Principles of Toxicology: THE BASIC SCIENCE OF POISONS at 14 (Klaasen ed., 5th ed., 1996); REFERENCE GUIDE ON TOXICOLOGY, in Federal Judicial Center, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 403 (2000).

²⁴ "The first conclusion to be drawn is that everyone in the population carries a fairly substantial burden of asbestos fibers in their lungs." A. Churg. *Nonneoplastic Disease Caused by Asbestos*, in PATHOLOGY OF OCCUPATIONAL LUNG DISEASE (Churg & Green, ed. 2nd 1998) at 293.

Hence, not every person who worked near a Grace asbestos product can demonstrate causation of injury. Here again, threshold determinations must be made under Daubert. The whole concept that "the dose makes the poison" is incorporated into the court's gatekeeping function under Daubert. A claimant thus has the burden of proving – by reliable and reproducible evidence – that (1) there is an established level of exposure to asbestos that causes disease in humans (i.e., general causation) and (2) the claimant himself was in fact exposed to the requisite dose (i.e., specific causation).²⁵ "[A] plaintiff in a toxic tort case must prove the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover." Wright v. Willamette Indus., Inc., 91 F.3d 1105, 1106 (8th Cir. 1996). Absent "accurate information on the level of [plaintiff's] exposure," a plaintiff's causation testimony must be excluded and summary judgment granted. Moore v. Ashland Chemical Co., 151 F.3d 269, 278 (5th Cir. 1998) (en banc), cert. denied, 526 U.S. 1064 (1999). Unless and until the claimant establishes the existence of a harmful dose - and further establishes actual exposure to an amount in excess of that dose - the trier of fact is left to guess whether that particular claimant's exposure was sufficient to cause disease. Guesswork is insufficient under Daubert or any other rule of evidence. In Mitchell v. Gencorp., 165 F.3d 778 (10th Cir. 1999), the Tenth Circuit affirmed summary judgment because the plaintiff had not shown sufficient reliable scientific information of "levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance." As the court explained: "Absent supporting scientific data, ... estimates and ... conclusions are little more than guesswork."

²⁵ See Reference Guide on Epidemiology, in Federal Judicial Center REFERENCEMANUAL ON SCIENTIFIC EVIDENCE 382 (2000) ("The plaintiff must establish not only that the defendant's agent is capable of causing disease, but also that it did not cause the plaintiff's disease.")

Guesses, even if educated, are insufficient to prove the level of exposure in a toxic tort case." Id. at 781.

It will be the claimants' burden to demonstrate through reliable scientific evidence the levels of exposure sufficient to cause both malignant and non-malignant asbestos-related disease. It will be their burden also to prove the occupational activities where the claimants' exposures to a Grace product reached such levels.

Following *Daubert* proceedings, Grace expects to move for summary judgment on all claims where the occupational activity that involved exposure to Grace products has not been proven (through evidence meeting *Daubert* standards) sufficient to cause the claimed disease.

c. Lack Of Compensable Injury

Grace also intends to move for summary judgment against those claims which do not provide evidence of a legally cognizable injury. Courts universally require the plaintiff to demonstrate "that the defendant had a duty of care which [was] breached, and that the breach proximately caused *legally cognizable injury*." *See. e.g., Faya v. Almaraz*, 329 Md. 435, 448, 620 A.2d 327 (1993) (emph. added)." The mere prospect of future harm, without any actual current harm, is not a legally cognizable personal injury. "Actual loss or damage resulting to the interests of another" is a necessary element of a negligence cause of action. "The threat of future harm, not yet realized, is not enough." PROSSER & KEETON ON TORTS § 30, at 165 (5th ed. 1984). ²⁶ A "mere change or alteration in some physical person, object or thing" does *not* constitute a legally compensable harm. "Physical changes or alterations may be either beneficial, detrimental or of no

This law also bars claims for medical monitoring costs. Medical monitoring claims present no present injury, only the risk of future injury. By definition, a risk of future injury is not compensable.

consequence to a person." A person suffers harm only "[i]n so far as physical changes have a detrimental effect" on that person. *Id.* § 7 cmt. b.

As is clear from the claims submitted to Grace historically, many claimants complain of "injury" from mere exposure to Grace products, but without any health problems or symptoms, Others complain of harmless pleural plaques or asymptomatic pleural thickening. Such conditions, however, are not compensable.

Pleural Plaques

Pleural plaques are opaque, rounded lesions of the pleura, which is a filmy, plastic wrap-like tissue membrane that surrounds certain inner surfaces as well as the exterior of the lungs.²⁷ Pleural plaques are clinically harmless and do not cause injury or impair lung function. They have been described in the medical literature as nothing more than "spots" that can be observed on a lung x-ray, since "by themselves, plaques do not cause loss of function or symptoms."²⁸ Specifically, pleural plaques do *not* cause shortness of breath, impair lung function, cause chest pain, cause any

See generally American Thoracic Society (ATS), The Diagnosis of Nonmalignant Diseases Related to Asbestos, AM. REV. RESPIR. DIS. 134: 363-68, 364 (1996). Pleural plaques typically are seen in the parietal pleura, which lines the inner chest wall, inner surface of the rib cage and diaphragm, as opposed to the visceral pleura, which surrounds the entire lung. Pleural plaques should generally be bilateral, that is, observed in both lungs.

According to Dr. Murphy, who headed the ATS committee that established criteria for diagnosing asbestosis, pleural plaques have been referred to as "beauty spots on the roentgenogram" or "markers of exposure" because "by themselves, plaques do not cause loss of function or symptoms." AM. REV. RESP. DIS. 136: 1516-17 (1987) (citations omitted). See also L. Brickman. The Asbestos Litigation Crisis, 13 CARDOZO L. REV. 1819, 1848 (1992), citing Gaensler, Asbestos-Related Pleural Plaques: Much Ado About Very Little. DRI Seminar 10/16-18/91 ("The investigators who initially described the connection between exposure to asbestos and pleural plaques called such lesions 'harmless scurrilous beauty marks on the chest film' because they found them neither associated with loss of function or symptoms nor precancerous. An extensive review of the literature 35 years later has revealed nothing to contradict these original impressions.")

abnormal physical symptoms, decrease life expectancy, or cause any known complications. In short, there is a medical consensus that pleural plaques are "an isolated radiographic finding" that "do not by themselves produce clinically significant reductions in pulmonary function."

Although some pleural plaques can become calcified and enlarged. "[e]ven strikingly large and bulky plaques do not cause measurable functional impairment, and when these patients complain of dyspnea the usual cause is asbestosis or chronic obstructive lung disease." As Dr. Browne has written in a leading text, "[w]hether calcified or not, pleural plaques alone are symptomless; dyspnea [shortness of breath], chest pain, abnormal physical signs and impairment of lung function are absent." Nor do pleural plaques increase the risk that the patient may contract an actual disease associated with asbestos. Pleural plaques are not precursors of lung cancer, mesothelioma or asbestosis. 33

²⁹ See K. Browne, Asbestos-Related Disorders, in OCCUPATIONAL LUNG DISORDERS (Parkes, ed. 3rd 1994) at 458 ("Plaques themselves have no effect on life expectancy and are not known to give rise to any complications.")

³⁰ See Jones, et al., The radiographic pleural abnormalities in asbestos exposure: Relationship to physiologic abnormalities, J. THORACIC IMG. 3: 57-65 (1988). See also A. Churg. Neoplastic Asbestos-Induced Disease, in Pathology of Occupational Lung Disease (Churg & Green, ed. 2nd 1998) at 339 (pleural disease "is still seen with considerable frequency, but it generally has little or no functional import"); Matters of Health and Safety Arising from the Use of Asbestos in Ontario, Toronto, Ontario Ministry of the Attorney General 1984 (hereinafter "Ontario Royal Commission") at 103. (Plaques are "not associated with clinical and functional abnormalities").

³¹ Gaensler et al., Thoracic Surgical Problems in Asbestos-Related Disorders, ANN, THORACIC SURG, 40:82-96, 93 (1985).

³² K. Browne. Asbestos-Related Disorders. in OCCUPATIONAL LUNG DISORDERS (Parkes, ed. 3rd 1994) at 455.

OCCUPATIONAL LUNG DISEASE, at 310 (Churg & Green, ed. 2d 1998) ("There is no evidence that plaques or diffuse pleural fibrosis are in any way precursors of mesothelioma"): W. Weiss, Asbestos-related Pleural Plaques and Lung Cancer, CHEST 103: 185-59 (1993) ("[T]he weight of the evidence favors the conclusion that persons with asbestosis-related pleural plaques do not have an increased risk of lung cancer in the (continued...)

Pleural Thickening

Pleural thickening is less common than pleural plaques. It typically affects the visceral pleura, the membrane surrounding the lungs. It can range from a thin, milky discoloration to a thicker fibrosis easily seen on x-ray. Pleural thickening is usually asymptomatic, although extensive diffuse thickening may have an adverse effect on lung function.

Courts Have Found That Pleural Plaques, Pleural Thickening And Asymptomatic Asbestosis Are Not Legal Injuries

The majority of courts that have considered the issue have found that pleural plaques and asymptomatic pleural thickening do not cause injury, harm, loss or detriment. They merely reflect a subclinical change in lung tissue, which is not actionable. "A mere change in the lining of the lung does not constitute an impairment or worsening of a bodily function, nor does it prevent the exercise of a bodily function." *In re Asbestos Litigation*, No. 87-09-24, 1994 WL 721763, at *3 (Del. Super. June 14, 1994), *rev'd on other grounds*, 670 A.2d 1339 (Del. Super. Ct. 1995). *See also. Owens-Corning v. Bauman*, 726 A.2d 745, 757 (Md. App.), *cert. denied*, 731 A.2d 970 (1999) ("[m]ere exposure to asbestos and cellular changes resulting from asbestos exposure, such as pleural plaques and thickening, alone *is not a functional impairment or harm*, and therefore, *do not constitute a legally compensable injury.*"); *Owens-Corning v. Bauman*, 726 A.2d 745, 757 (Md. App.), *cert. denied*, 731 A.2d 970 (1999) (cause of action for asbestos-related personal injury "does not arise until the asbestos fibers inhaled into the lungs cause functional impairment"), *citing ACandS. Inc. v. Abate*, 710 A.2d 944, 981-982 (Md. Ct. Spec. 1998), *cert. denied*, 713 A.2d 979 (1998) ("the condition known as pleural plaques, or even generalized pleural thickening,

absence of parenchymal asbestosis").

unaccompanied by disabling consequences or physical impairment, is not a compensable injury as a matter of law"); Simmons v. Pacor. Inc., 674 A.2d 232, 236-37 (Pa. 1996) (Because scarring of lung tissue is a "mere physical change that was unaccompanied by any detrimental effect." plaintiffs suffered no harm and could not recover for asymptomatic pleural thickening.); In re Hawaii Federal Asbestos Cases, 734 F.Supp. 1563, 1567 (D. Haw. 1990) ("A claimant's subjective testimony as to shortness of breath and fatigue without more is not sufficientPlaintiff must show a compensable harm by adducing objective testimony of a functional impairment due to asbestos exposure."); Wright v. Eagle-Picher Indus., Inc., 565 A.2d 377 (Md. 1989) (pleural plaques are non-compensable injury when unaccompanied by any symptoms or functional impairment) (all emph. added)

Likewise, in *Bernier v. Raymark Industries, Inc.*, 516 A.2d 534 (Me. 1986), the Maine Supreme Court concluded that subclinical injury is not actionable. "Even assuming that any inhalation of asbestos dust immediately causes microscopic injury to lung tissues, we conclude that the subclinical injury resulting from such inhalation is 'insufficient to constitute the actual loss or damage to a plaintiff's interest required to sustain a cause of action under generally applicable principles of tort law." *Id.* at 543. The *Bernier* court was quoting from a FELA case, *Schweitzer v. Consolidated Rail Corp.*, 758 F.2d 936, 942 (3d Cir. 1985), *cert. denied*, 474 U.S. 864, 106 St. 183 (1985). As the U.S. Supreme Court has recognized in FELA cases. "the words 'physical impact' do not encompass every form of 'physical contact'. And, in particular, they do not include a contact that amounts to no more than an exposure." *Metro-North Commuter Railroad Co. v. Buckley*, 521 U.S. 424, 432 (1997): *see also Amendola v. Kansas City Southern Railway Co.*, 699 F.Supp. 1401 (W.D. Mo. 1988) (inhalation of asbestos fibers alone did not represent physical injury sufficient to support a claim).

Courts also have found that asymptomatic asbestosis is not a legally cognizable injury. For example, in *Burns v. Jaquays Mining Corp.*, 752 P.2d 28 (Ariz. App. 1987), the court granted summary judgment to an asbestos mill owner with regard to subclinical asbestosis claims because subclinical injuries do not amount to physical harm. "[U]ntil the asbestosis manifests itself one can only speculate as to the debilitating effects the plaintiff will suffer. Not all asbestosis is one hundred percent debilitating." Consequently, the court stated, "[w]e see no reason to depart from traditional tort concepts and allow recovery for injuries before any disease becomes manifest." *Id.* at 31. The court reasoned that a contrary rule would give rise to a cause of action for countless plaintiffs who are healthy and might never manifest injury. Furthermore,

proof of damages in such cases would be highly speculative, likely resulting in windfalls for those who never take ill and insufficient compensation for those who do. Requiring manifest injury as a necessary element of an asbestos-related tort action avoids these problems and best serves the underlying purposes of tort law: the compensation of victims who have suffered.

Id. at 30, (quoting Schweitzer v. Consolidated Rail Corp., 758 F.2d 936, 942 (3d Cir. 1985)).

Similarly, in *Taylor v. Owens-Corning Fiberglas Corp.*, 666 A.2d 681, 687 (Pa. Super. Ct. 1995) the Pennsylvania Superior Court found that "a plaintiff... must suffer discernible physical symptoms to have a compensable injury." Several of the plaintiffs whose cases had been consolidated in *Taylor* had been diagnosed with asbestosis but had no symptoms attributable to asbestos exposure. The court found that none of the plaintiffs had an injury sufficient to sustain a legal cause of action. "[I]f a plaintiff is able to 'lead active, normal [life], with no pain or suffering, no loss of an organ function' he does not have a compensable injury." *Id.* (quoting *Giffear v. Johns Manville Corp.*, 632 A.2d 880, 887 (Pa. Super. 1993)).

Given this precedent. Grace will ask the Court to decide that claims of "injury" predicated on pleural plaques, asymptomatic asbestosis or any other subclinical condition are not compensable.

d. Claims Supported By Unreliable Diagnostic Data Cannot Survive *Daubert* Scrutiny

A further problem with asbestosis claims is that they turn on diagnostic assessments that are neither reproducible nor reliable unless they meet specific standards and are appropriately verified. A claimant must demonstrate that the test method performed in his or her case is reliable and admissible. See In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 742, 745 (3d Cir.1994), cert. denied sub nom General Elec. Co. v. Ingram. 513 U.S. 1190 (1995) (sponsoring party must demonstrate expert's findings are based on the scientific method and are reliable; any failure to do so renders testimony inadmissible). The scientific method relied upon may not be based on subjective speculation. Daubert, 509 U.S. at 590. The methodology must be real and it must produce consistent results, meaning, it must be reproducible. See id. at 590, n. 9. Even if a test is generally reliable, testing is inadmissible if performed in an unreliable manner. See, e.g., Metropolitan St. Louis Equal Housing Opp'y Council v. Gordon Gundaker Real Estate Co., 130 F.Supp.2d 1074, 1082-83 (E.D. Mo. 2001) (excluding expert testimony based on flawed testing protocols).

In the asbestos context, data from two types of test results, while widely used to support mass claim filings, can be unreliable, manipulable and not reproducible: (1) ILO scores — which are based on subjective interpretations of lung x-rays — have been shown to be highly unreliable unless independent doctors make multiple corroborative readings, and (2) lung function testing, known as a pulmonary function test ("PFT"), is highly manipulable and must be

reproduced in accordance with defined procedures before a claimant can be deemed to have a real impairment. While these tests can be scientifically valid when performed in accordance with recognized procedures and standards, they are invalid if those procedures and standards are not followed. In the latter case, such test data will lack sufficient reliability, reproducibility and scientific validity to be admissible under *Daubert*.

This is not merely an academic concern for Grace. As discussed in Part I above, the recent surge in claims against Grace has come after mass screenings were performed by a small number of plaintiff firms. ILO and PFT tests have yielded massive numbers of claims for nonmalignant conditions. The task of determining whether these claims are supported will be difficult (but necessary) to ensure that only claims that are based upon reliable science are permitted to proceed. Again, appointment of a Rule 706 panel may be appropriate to assist the Court in performing its role as a "gatekeeper" under *Daubert*. Independent experts also could be enlisted to advise the Court in screening procedures necessary to assure that only claims supported by reliable diagnostic data *per se* are allowed to go forward.

ILO Tests

There are two major and interconnected problems with ILO scores – variability and subjectivity. Numerous studies have shown that lung x-rays are interpreted with tremendous variability by different readers (inter-observer variability) and even by the same reader at different times (intra-observer variability). The ILO itself acknowledges that "there is significant variation in repeated readings of the same radiograph, not only from reader to reader, but also between readings by the same reader."³⁴

³⁴ ILO 1980 International Classification of Radiographs of the Pneumoconioses International Labour (continued...)